

**REMARKS**

Claims 1-8, and 13 are pending in this application. In the instant correspondence, claim 1 has been amended without prejudice to prosecuting the same (or a similar) claim in a subsequently filed patent application. The Applicant also adds new claims 16 and 17.<sup>1</sup>

Claims 1-8, and 13 were rejected. The Examiner made the following rejections:

- 1) The Examiner rejects claims 1-8, and 13 under 35 U.S.C. § 103(a), as allegedly being unpatentable over Caruso (U.S. Patent 6,043,244) or Plachetka (U.S. Patent 5,872,145). In addition, the Examiner rejects claim 3, under 35 U.S.C. § 103(a), as allegedly being unpatentable over Caruso or Plachetka in combination with Azia *et al.* (U.S. Patent 4,758,423) or Plachetka *et al.* (U.S. Patent 6,495,535).

The Applicant's remarks are presented in the same order as the rejections set out above.

**1) The Claims Are Not Obvious**

In the Office Action Response, filed on May 04, 2004, the Applicant submitted the Examiner failed to make a case in support of the pending rejections under 35 U.S.C. 103. The Applicant hereby renews this argument in response to the Examiner's pending rejections under 35 U.S.C. 103. In addition to these previously articulated arguments, the Applicant submits the cited art teaches away from the currently claimed embodiments of the present invention.

As presented above, the pending claims teach (in part) the treatment of migraine with the administration of a fast dissolve formulation comprising two active ingredients and one or more inactive ingredients, wherein the two active ingredients are dihydroergotamine and a steroid and one of the inactive ingredients is a pH adjusting agent. In contrast, Caruso teaches that:

“...in addition to the antimigraine drug and antimigraine-potentiating amount of an NMDA receptor blocker or substance that blocks a major intracellular consequence of NMDA receptor activation, the therapeutic composition herein can contain at least one other pharmacologically active substance e.g., caffeine (a stimulant), an antiemetic drug such as metoclopramide, domperidone, belladonna alkaloids and phenothiazines such as chlorpromazine, prochlorperazine, and promethazine, a non-narcotic analgesic, e.g., acetaminophen or a nonsteroidal

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<sup>1</sup> Support for the new and amended claims is found, in the application as filed, on page 16, ll. 16-25.

*anti-inflammatory* drug such as aspirin, diclofenac, diflusal, etodolac, fenbufen, fenoprofen, flufenisal, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, meclofenamic acid, mefenamic acid, nabumetone, naproxen, oxaprozin, phenylbutazone, piroxicam, sulindac, tolmetin, zomepirac, and the like.” U.S. Patent 6,043,244, Co. 8, ll. 11-27. (emphasis added).

Despite providing a laundry list of supplemental nonsteroidal anti-inflammatory compounds, Caruso is conspicuously silent on co-formulating steroids with any of the anti-migraine formulations taught in the ‘244 patent. The Applicant, however, appreciates that steroids have beneficial therapeutic properties<sup>2</sup> (vis-à-vis the treatment of migraine) and that sublingual administration of steroids allows for a prospective reduction of dose (and, thereby, reduction of side effects and toxicities) given: i) the direct transmucosal delivery into the bloodstream and ii) a reduction of the first pass effect associated with enteral administration. For example glucocorticoid, in part, stimulates gluconeogenesis and inhibits the uptake of glucose from muscle and adipose tissue. These physiological effects would be desirable in supplementing the action of DHE in methods for the treatment of migraine.

Caruso, therefore, teaches away from the claimed embodiments of the present invention and fails to provide any motivation for one skilled in the art to recapitulate the same. Given the ‘244 to Caruso would likely lead an investigator in a direction divergent from the path taken by the Applicant, the ‘244 patent may not support a rejection under 35 U.S.C. 103.<sup>3</sup> See, *Paro-Ordnance Manufacturing v. SGS Importers International*, 37 USPQ2d 1130, 1131 (Fed. Cir. 1994).

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<sup>2</sup> The Applicant also notes there is no obligation to describe the underlying mechanism of the claimed methods and the following remarks in no way limit the scope of the invention as claimed.

<sup>3</sup> The Applicant also notes the other art cited by the Examiner in support of the pending rejections under 35 U.S.C. 103 (e.g. U.S. Patent 5,872,145, U.S. Patent 4,758,423, and U.S. Patent 6,495,535) are silent on the incorporation of steroids into any formulation taught therein.

**CONCLUSION**

The Applicant believes the arguments set forth above traverse the Examiner's pending rejections and, therefore, requests these grounds for rejection be withdrawn. Should the Examiner believe a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned collect.

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Peter G. Carroll  
Registration No. 32,837

MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 350  
San Francisco, California 94105  
415.904.6500